

OCT 1 9 2000

K001795
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ATTACHMENT H

SMDA REQUIREMENTS

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer: Automatic Liquid Packaging, Inc.
2200 Lake Shore Drive
Woodstock, IL 60098

Regulatory Affairs Contact: John Brda

Telephone: 815/338-9500

Sponsor: Barry L. Farris
Avitro LLC
276 Kingsbury Grade - Suite 104
Zephyr Cove, NV 89448
Phone: 775/588-6899

Date Summary Prepared: February, 2000

Common Name: 10 and 100 Units/mL Heparin Vascular Access Flush Device

Classification: Class II per 21CFR & 868.5860

Predicate Device: Vital Signs 10 & 100 Units/mL Heparin Vascular Access Flush Device

Description: The only ingredient in the solution other than water is Heparin and Sodium Chloride; there are no preservatives or stabilizers.

The container is manufactured of 100% low-density polyethylene (LDPE). The 10 Unit/mL Heparin containers are clear; and the 100 Unit/mL Heparin containers are clear in color.

The solution is sterile, aseptically filled and is hermetically sealed for single use only.

Intended Use: 10 and 100 USP Units/mL Heparin Vascular Access Flush Devices defined as an accessory to a device that is intended for use to maintain patency of an indwelling intravenous Access Flush Device. (IVAD).

SMDA REQUIREMENTS CONTINUED

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial Equivalence:

The Avitro LLC, 10 and 100 USP Units/mL Heparin Vascular Access Flush Device Solution is substantially equivalent to the Vital Signs 10 and 100 Vascular Access Flush Device Solution in that:

- The intended use is the same
- The performance attributes are the same

Summary of testing:

All materials used in the fabrication of Avitro LLC, 10 and 100 USP units mL Heparin Vascular Access Flush Device Solution were evaluated through biological qualification safety tests as outlines in ISO 10993 Part-1 "Biological Evaluation of Medical Devices." These material also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 19 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Avitro LLC
C/O Mr. John Brda
Regulatory Affairs
Automatic Liquid Packing, Incorporated
2200 Lake Shore Drive
Woodstock, Illinois 60098

Re: K001795
Trade Name: 10 and 100 USP units/mL Heparin Vascular
Access Flush Device
Regulatory Class: II
Product Code: FOZ
Dated: September 5, 2000
Received: September 25, 2000

Dear Mr. Brda:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

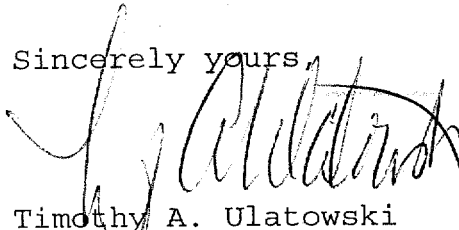
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001795

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ATTACHMENT D

510(K) Number (if known)

Unknown

Device Name:

10 and 100 USP Units/mL Heparin Vascular Access Flush
Device

Indications for Use:

10 and 100 USP Units/mL Heparin Vascular Access Flush
Devices defined for use to maintain patency of indwelling
Intravenous Access Device (IVAD).


(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

or

Over-The Counter Use ☐


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001795

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